

INTERNATIONAL SEARCH REPORT

International application No. -

PCT/US04/30724

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 9/14
US CL : 424/489

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/489

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
West Search

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,290,991B1 (ROSER et al), 18 September 2001, column 3, lin 50-55 and column 4, lin 20-45.	1-46
X	US 6,482,830 B1 (REDEKAR et al) 19 November 2002, column 4, lin 60-65 and column 20, lin 30-55.	1-46

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *B* earlier application or patent published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another claim or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

Z document member of the same patent family

Date of the actual completion of the international search

09 December 2004 (09.12.2004)

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1459
Alexandria, Virginia 22313-1459
Facsimile No. 703-305-3230

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Authorized officer

Reiford Berko

Telephone No. 571-272-1600

[received by the International Bureau on 22 APR 2005 (22.04.05);
original claims 1 and 20 have been replaced by amended claims 1 and 20
(2 pages)]

What is claim is:

1. Particles for drug delivery by inhalation, comprising at least one active ingredient which is non-crystalline, wherein the outer surface of the particles is substantially smooth.
2. Particles according to Claim 1, further comprising a second or more active(s) and/or one or more excipients.
3. Particles for drug delivery according to Claim 1 or Claim 2, the particles containing a plurality of active ingredients which active ingredients are non-crystalline.
4. Particles according to Claim 3, the outer surface of the particles being substantially smooth.
5. Particles according to Claim 3, the particles being substantially spherical.
6. Particles according to Claim 5, the particles being oblate spheroidal.
7. Particles according to Claim 3, the particles being substantially oval.
8. Particles according to Claim 3, the particles being substantially elliptical.
9. Particles according to any preceding claim, having a particle size in the range $0.5\mu\text{m} - 5\mu\text{m}$.
10. Particles according to Claim 9, the particle size being between $1\mu\text{m}$ to $3\mu\text{m}$.
11. Particles according to Claim 9 when dependent on Claim 7 or Claim 8, the longer axis of an oval or elliptical particle having a length between $1\mu\text{m}$ to $3\mu\text{m}$.
12. Particles according to any preceding Claim, the particles being electrically uncharged.
13. Particles according to any preceding claim, provided by a method selected from the group comprising rapid expansion of supercritical solutions, precipitation from gas saturated solutions, gas anti-solvent systems, aerosol solvent extraction systems and spray drying processes.
14. Particles according to any preceding claim, there being from two to four active ingredients.

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15. Particles according to any preceding claim, comprising a pharmaceutically acceptable particular excipient or excipients.
16. Particles according to any preceding claim, the active ingredients comprising a β_2 -agonist and a steroid.
17. Particles according to Claim 15, comprising fluticasone-dipropionate and salmeterol xinafoate.
18. Particles according to any one of Claims 1 to 15, comprising formoterol and budesonide.
19. Particles for drug delivery according to any of claims 2 to 18, the or each excipient being soluble in conditions obtaining in the nose, lung(s) or mouth of a human or animal.
20. An inhalation composition, comprising particles which incorporate at least one active ingredient which is non-crystalline, wherein the particles have an outer surface that is substantially smooth.
21. A composition according to Claim 20, further comprising a second or more active(s) and/or one or more excipients.
22. A composition according to Claim 20 or 21, the particles containing a plurality of active ingredients, which active ingredients are non-crystalline.
23. A composition according to Claims 20 to 22, there being from two to four active ingredients.
24. A composition according to any of Claims 21 to 23, the particles comprising a pharmaceutically acceptable excipient within the particle.
25. A composition according to any of Claims 21 to 24, the particles comprising a pharmaceutically acceptable excipient or excipients where a main excipient is in a greater proportion than the active or actives.
26. A composition according to Claim 25, the main excipient being Mannitol or PVP.
27. A composition according to any of Claims 21 to 26, comprising one or more additional carrier excipient(s).

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